

CLAIMS

1. A solid composition comprising a plurality of particles, said particles comprising a low-solubility drug and a poloxamer, at least a substantial portion of said drug in said particles being amorphous, said amorphous drug being in intimate contact with said poloxamer in said particles, and said drug and said poloxamer together comprising at least 50 wt% of said particles, wherein said drug has a glass transition temperature of at least 50°C.
2. A solid composition comprising a plurality of particles, said particles comprising a low-solubility drug and a poloxamer, at least a substantial portion of said drug in said particles being amorphous, said amorphous drug being in intimate contact with said poloxamer in said particles, and said drug and said poloxamer together comprising at least 50 wt% of said particles, wherein said drug has a Log P value of greater than about 6.5.
3. The solid composition of claim 2 wherein said drug has a glass transition temperature of at least 50°C.
4. The solid composition of claim 1 wherein said drug has a Log P value of greater than about 6.5.
5. The solid composition of any of claims 1-4 wherein said glass transition temperature of said drug is at least 60°C.
6. The solid composition of any of claims 1-4 wherein said glass transition temperature of said drug is at least 70°C.
7. The solid composition of any of claims 1-4 wherein said Log P value of said drug is at least 7.0.
8. The solid composition of any of claims 1-4 wherein said Log P value of said drug is at least 8.

9. The solid composition of any of claims 1-4 wherein said drug has a melting point of T_m in °K, and a glass transition temperature of $T_{g,drug}$ in °K, and wherein the ratio of $T_m/T_{g,drug}$ is less than about 1.4.
- 5 10. The solid composition of claim 8 wherein said ratio $T_m/T_{g,drug}$ is less than about 1.35.
11. The solid composition of claim 9 wherein said ratio $T_m/T_{g,drug}$ is less than about 1.3.
- 10 12. The solid composition of any of claims 1-4 wherein said drug is almost completely amorphous.
13. The solid composition of any of claims 1-4 wherein said drug
15 constitutes at least about 40 wt% of said particles.
14. The solid composition of claim 13 wherein said drug constitutes at least about 45 wt% of said particles.
- 20 15. The solid composition of claim 14 wherein said drug constitutes at least 50 wt% of said particles.
16. The solid composition of any of claims 1-4 wherein less than
10 wt% of said drug in said composition crystallizes during storage for three weeks at
25 25°C and 10% relative humidity.
17. The solid composition of any of claims 1-4 wherein said dispersion, following administration to an *in vivo* or *in vitro* aqueous environment of use, provides concentration enhancement relative to a control composition consisting
30 essentially of said drug alone, wherein said concentration enhancement is characterized by at least one of
- (a) a maximum drug concentration in said aqueous environment of use that is at least 1.25-fold that provided by said control composition; and

- 5 (b) an area under the concentration versus time curve in said aqueous environment of use for any period of at least 90 minutes between the time of introduction of said dispersion into said aqueous environment of use and about 270 minutes following introduction to said aqueous environment of use that is at least 1.25-fold that provided by said control composition.

10 18. The solid composition of any of claims 1-4 wherein said dispersion, following administration to an *in vivo* environment of use, provides concentration enhancement relative to a control composition consisting essentially of said drug alone, wherein said concentration enhancement is characterized by at least one of

- 15 (a) a maximum concentration in the blood that is at least 1.25-fold that provided by said control composition; and
(b) a relative bioavailability that is at least 1.25 fold relative to said control composition.

20 19. A pharmaceutical composition comprising
(1) the solid composition of any of claims 1-4, and
(2) a concentration-enhancing polymer;
wherein said concentration-enhancing polymer is present in an amount sufficient that said pharmaceutical composition, following administration to an *in vivo* or *in vitro* aqueous environment of use, provides concentration enhancement relative to a control composition consisting essentially of said solid composition.

25 20. The pharmaceutical composition of claim 19 wherein said concentration-enhancing polymer is selected from the group consisting of hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, carboxymethyl
30 ethylcellulose, and mixtures thereof.

21. The pharmaceutical composition of claim 19 wherein said concentration enhancement is characterized by at least one of

- 5 (a) a maximum drug concentration in said aqueous environment of use that is at least 1.25-fold that provided by said control composition; and
- (b) an area under the concentration versus time curve in said aqueous environment of use for any period of at least 90 minutes between the time of introduction of said dispersion into said aqueous environment of use and about 270 minutes following introduction to said aqueous environment of use that is at least 1.25-fold that provided by said control composition.
- 10 22. The pharmaceutical composition of claim 19 wherein said use environment is *in vivo* and said concentration enhancement is characterized by at least one of
- 15 (a) a maximum concentration in the blood that is at least 1.25-fold that provided by said control composition; and
- (b) a relative bioavailability that is at least 1.25 fold relative to said control composition.
- 20 23. A process for preparing a solid composition comprising the steps
- (1) forming a solution consisting essentially of a low-solubility drug, a poloxamer, and a solvent; and
- (2) removing said solvent from said solution to form said solid composition consisting essentially of said low-solubility drug and said poloxamer, at least a substantial portion of said drug in said composition being amorphous;
- 25 wherein said drug has a glass transition temperature of at least 50°C.
24. A process for preparing a solid composition comprising the steps
- (1) forming a solution consisting essentially of a low-solubility drug, a poloxamer, and a solvent; and
- 30 (2) removing said solvent from said solution to form said solid composition consisting essentially of said low-solubility drug and said poloxamer, at least a substantial portion of said drug in said composition being amorphous;
- 35 wherein said drug has a Log P value greater than about 6.5.

25. The process of claim 23 or 24 wherein step (2) is selected from the group consisting of spray-drying, spray-coating, rotoevaporation and evaporation.

5 26. The product of the process of claim 23 or 24.